

## REMARKS

Reconsideration of the rejections based upon the foregoing amendments and the following remarks is respectfully requested.

**A. Claims 7-11 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Specifically, the Office Action alleges that there is no antecedent basis for the phrases “first electrodes” in line 12, “second electrodes” in line 13, and “third electrodes” in line 17 of claim 7. It is respectfully submitted that claim 7 has been amended herein in order to make references to a “pair of electrodes” in each of the instances pointed out by the Examiner, thereby providing antecedent basis for the phrases in lines 12, 13 and 17. It is respectfully submitted that claims 7-11, as amended, therefore comply with 35 U.S.C. §112, second paragraph.

**B. Claims 1-5 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) in view of Beaty et al. (US 6,645,368 B1) (“Beaty”). Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Neel in view of Beaty, and further in view of Feldman et al. (US 6,592,745 B1) (“Feldman”). Claims 7-15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Neel in view of Feldman.**

Claim 1 specifically requires “applying a first test signal to at least one of the first pair of electrodes; measuring a first response to the first test signal; maintaining the first pair of electrodes in an inoperative state after the measuring the first response; applying a second test signal to at least one

of the second pair of electrodes, wherein the second test signal is a signal having an AC component; measuring a second response to the second test signal; and performing a measurement upon the biological fluid after the measuring the second response.” It is respectfully submitted that the above-recited combination of steps is not taught or suggested in the prior art of record.

The Office Action concedes that Neel teaches the use of a DC signal applied to dose sufficiency electrodes, but does not disclose the use of a signal having an AC component. In an attempt to cure this deficiency, the Office Action suggests that Beaty discloses applying an AC signal to measurement electrodes to determine sample volume sufficiency, therefore it would have been obvious to use a signal having an AC component with the dose sufficiency electrodes of Neel.

It is respectfully submitted that, rather than rendering the claimed invention obvious, the combination of Neel and Beaty teach away from the present invention. Neel teaches the use of a separate pair of dose sufficiency electrodes and the application of a DC signal thereto. The reason that Neel uses a separate pair of dose sufficiency electrodes (i.e. separate from the measurement electrodes) is that Neel teaches that applying a DC signal to the measurement electrodes for purposes of determining dose sufficiency will thereby disturb the reaction between the sample and the reagent in the critical region of the sample chamber for measurement. By applying the DC signal to the dose sufficiency electrodes separate and distinct from the measurement electrodes, and leaving an open circuit between the measurement electrodes, the stoichiometry of the measurement region is not disturbed until the measurement sequence is ready to begin. See Neel, col. 14, line 55 to col. 15, line 25.

Beaty, on the other hand, teaches that the adequacy of the sample volume can be determined by applying an AC signal of proper level directly to the measurement electrodes, without the need for separate dose sufficiency electrodes. This is because an AC signal at the proper level will not drive the sample redox (reduction-oxidation) reaction in one direction. Therefore, a combination of Neel

and Beaty teaches that the separate dose sufficiency electrodes of Neel are unnecessary since the application of an AC signal to the measurement electrodes achieves the same result without the need for an additional pair of dose sufficiency electrodes. There is nothing in the combination that would suggest to one of ordinary skill in the art that a signal having an AC component should be applied to separate dose sufficiency electrodes since Beaty demonstrates that this is unnecessary when using an AC signal. Feldman does not lend any weight or support to the findings of the Office Action because it simply does not relate to the use of a signal having an AC component.

The Office Action attempts to counter the above teachings by alleging that Neel places the fill-detect electrodes 28 and 30 downstream from the measurement electrodes in order to ensure that 1) the sample has covered the reagent layer and the measurement pair of electrodes, and 2) that the sample has sufficiently mixed with the reagent (Office Action, p. 3). It is respectfully submitted that the teaching of Beaty to apply an AC signal to the measurement electrodes accomplishes (1) above, namely determining that there is adequate sample volume to cover the electrodes and the reagent covering the electrodes – that is the reason that Beaty performs this test. As to point (2), there is no teaching in Neel that the device disclosed therein can actually detect sufficient mixing of the sample and the reagent. Neel is able to determine that the sample has covered the reagent, but he teaches no method of detecting that the sample has sufficiently mixed with the reagent. Despite the portion of the Neel disclosure quoted in the Office Action, one skilled in the art would immediately recognize that there is no teaching in Neel in order to substantiate such a claim. As Beaty also teaches that application of an AC signal to the measurement electrodes can detect adequate sample volume to cover the electrodes and the reagent covering the electrodes, the fill-detect electrodes of Neel would therefore become superfluous in the combination of Neel and Beaty. It is only Applicants' disclosure in the present application that recognizes that the sample flow front in capillary chambers can have various shapes and that some of these shapes can cause false indications of sufficient sample size in

the prior art devices. Accordingly, only Applicants' disclosure recognizes that the application of an AC signal to a separate pair of non-measurement electrodes provides valuable benefits, as discussed in Applicants' specification:

An advantage of the parallel dose sufficiency electrode design of FIGs. 35 and 36, when used with AC excitation, is that there is substantially no electrical communication between the electrodes until the sample covers at least a portion of the edges along the electrode gap. Therefore, a sample exhibiting the concave flow front of FIG. 35A, where the illustrated sample is touching both of the dose sufficiency electrodes 3508,3510 but is not touching the electrode edges along the gap, will not produce any significant electrical communication between the dose sufficiency electrodes. The test meter will therefore not form a conclusion of dose sufficiency until the sample has actually bridged the dose sufficiency electrodes between the electrode edges along the gap. This will happen only after the rear-most portion of the concave flow front has reached the dose sufficiency electrodes 3508,3510, at which point the sample has completely covered the measurement zone over the measurement electrodes. As can be seen in FIG. 35B, convex sample flow fronts will activate the dose sufficiency electrodes 3508,3510 as soon as the flow front reaches the dose sufficiency electrodes (at which point the sample has completely covered the measurement zone over the measurement electrodes).

(Applicants' specification, p. 54, lines 14-29). To allege that the desirability of such use of AC signals is obvious in view of the prior art is to use impermissible hindsight, using against Applicants what only Applicants have taught.

With respect to the discussion on page 4 of the Office Action regarding the various electrical contacts disclosed by Beaty, it is respectfully submitted that Beaty discloses only two electrodes on the test strip, and that the number of electrical contacts present in the connector in the test meter is irrelevant to number of electrodes on the test strip. The methodology of Beaty is performed with only two electrodes, and could thus be performed with only two electrodes in a combination of Beaty and Neel, making the fill-detect electrodes of Neel unnecessary.

Finally, one aspect of the proposed combination of Neel and Beaty that has not been explained in the Office Action is why the combination teaches application of an AC signal to the fill-

detect electrodes of Neel. As conceded on the second paragraph of page 4 of the Office Action, “it is not clearly apparent that removing the sample sufficiency electrodes 28 and 30 of Neel would be redundant as Applicant alleges if the sample sufficiency AC signal of Beaty is just applied to the measurement electrodes 22 and 24 of Neel.” If this is indeed the case, then the combination teaches applying a DC signal to the fill-detect electrodes and the combination still does not meet the limitations of Applicants’ claim 1. Beaty teaches application of an AC sample sufficiency signal to the measurement electrodes. Neel teaches the use of a DC signal on separate fill-detect electrodes. If the use of the Beaty AC signal on the measurement electrodes of Neel still requires the use of the fill-detect electrodes, as alleged in the Office Action, then the only teaching of the use of the fill-detect electrodes in the combination is the application of a DC signal thereto, which does not meet the limitations of Applicants’ claim 1. Nowhere does the combination of Neel and Beaty teach that there is any reason to apply an AC signal to electrodes downstream from the measurement electrodes. Such is only taught in the present application. It is therefore respectfully submitted that Applicants’ claim 1 is allowable in view of the references of record.

Claims 2-6 and 16 depend from claim 1 and therefore include all of the limitations of claim 1. It is therefore respectfully submitted that claims 2-6 and 16 are allowable over the references of record for at least the same reasons set forth above with respect to claim 1.

Claim 7 specifically requires “a third pair of electrodes in operative communication with the chamber” and “third measuring an analyte concentration of the biological fluid using the third electrodes.” It is respectfully submitted that the Neel et al. reference does not disclose the above-recited element of Applicants’ claim 7. Neel et al. discloses only two pairs of electrodes. The Office Action alleges that this deficiency in Neel et al. is cured by Feldman et al., which discloses three working electrodes. However, Feldman et al. does not teach or suggest the provision of any type of electrodes for measuring fill time, let alone the provision of a separate set of electrodes for analyte

measurement and fill time measurement. Neel et al. actually teaches directly away from the claimed invention by specifying that the measurement electrodes should be used as part of the fill time measurement. Therefore, the combination of Neel et al. and Feldman et al. cannot teach or suggest the provision of a separate set of electrodes for analyte measurement and fill time measurement. It is therefore respectfully submitted that Applicants' claim 7 is allowable over the references of record.

Claims 8-11 depend from claim 7 and therefore include all of the limitations of claim 7. It is therefore respectfully submitted that claims 8-11 are allowable over the references of record for at least the same reasons set forth above with respect to claim 7.

Claim 12, as amended, specifically requires "determining a fill time of the chamber based upon the first response and the second response; . . . determining a concentration of an analyte in the biological fluid using the third response." It is respectfully submitted that the Neel et al. reference does not disclose the above-recited element of Applicants' claim 12. Neel et al. discloses only two pairs of electrodes. The Office Action alleges that this deficiency in Neel et al. is cured by Feldman et al., which discloses three working electrodes. However, Feldman et al. does not teach or suggest the provision of any type of electrodes for measuring fill time, let alone the provision of a separate set of electrodes for analyte measurement and fill time measurement. Neel et al. actually teaches directly away from the claimed invention by specifying that the measurement electrodes should be used as part of the fill time measurement. Therefore, the combination of Neel et al. and Feldman et al. cannot teach or suggest the provision of a separate set of electrodes for analyte measurement and fill time measurement. It is therefore respectfully submitted that Applicants' claim 12 is allowable over the references of record.

Claims 13-15 depend from claim 12 and therefore include all of the limitations of claim 12. It is therefore respectfully submitted that claims 13-15 are allowable over the references of record for at least the same reasons set forth above with respect to claim 12.

Claim 16 depends from claim 12 and therefore includes all of the limitations of claim 12. The addition of the Beaty reference does nothing to cure the deficiencies of the Neel and Feldman combination. It is therefore respectfully submitted that claim 16 is allowable over the references of record for at least the same reasons set forth above with respect to claim 12.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and respectfully request such action. Applicants respectfully request that the Examiner telephone the undersigned attorney for Applicants at 317-634-3456 if the Examiner does not find that all claims are in condition for allowance as presented herein.

Respectfully submitted,

By: /troy j. cole/  
Troy J. Cole  
Reg. No. 35,102  
Woodard, Emhardt, Moriarty,  
McNett & Henry LLP  
Chase Tower  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
(317) 634-3456